DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 21, 2015

Nanotherapeutics, Incorporated
Doris Snow, Ph.D.
Senior Director Regulatory Affairs
13859 Progress Boulevard, Suite 300
Alachua, Florida 32615

Re: K142104
Trade/Device Name: NanoFUSE® DBM
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: December 16, 2014
Received: December 19, 2014

Dear Dr. Snow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

nanotherapeutics

INDICATIONS FOR USE

510(k) Number (if known): K142104

Device Name: NanoFUSE® DBM

Indications for Use:

NanoFUSE® DBM is indicated to be gently placed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure (i.e., the extremities, pelvis and posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NanoFUSE® DBM must be used with autograft as a bone graft extender in the posterolateral spine. The product provides a bone graft substitute that remodels into the recipient's skeletal system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

nanotherapeutics

SECTION 05 **510(k) SUMMARY OF SAFETY & EFFECTIVENESS**

NanoFUSE® DBM

Date: December 16, 2014

Submitted by: Nanotherapeutics, Inc.
13859 Progress Blvd., Suite 300
Alachua, FL 32615

Representative: Doris Snow, Ph.D.
Sr. Director, Regulatory Affairs
Phone: (386) 462-9663
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Proprietary Name: NanoFUSE® DBM

Common Name: Bone Void Filler, Bone Graft Substitute

Classification Name: Filler, Calcium Sulfate Preformed Pellets, 21 CFR § 888.3045

Classification Codes: MBP - Class II

Predicate Devices:

Trade/Proprietary Name	Manufacturer	510(k) Number
NanoFUSE® DBM	Nanotherapeutics	K120279

Description: NanoFUSE® DBM is a malleable, putty-like, bone-void filler for use in general orthopedic applications. The product is comprised of human demineralized bone matrix (DBM) and synthetic calcium phosphor-silicate particulate material particles (45s5 bioactive glass), both coated with gelatin derived from porcine skin. These coated particles are packaged dry in a single use, polypropylene syringe (20 cc or 3 cc), double-wrapped in peel-back pouches, and final packaged in a dust cover paperboard carton. The 20 cc syringe will be filled with either of two different fill quantities of dry powder, identified as 10 cc or 5 cc final product volume. The 3 cc syringe will be filled with dry powder, identified as 2 cc final product volume. NanoFUSE® DBM is intended for single patient use only.

At point of use, the surgeon will reconstitute the product with an appropriate sterile solution of his/her choice (sterile saline, water for injection, or autologous whole blood). The coated particles rehydrate in less than 30 seconds and do not require mixing to form a uniform paste or putty. The material is then gently extruded by the surgeon into the appropriate bone voids. NanoFUSE® DBM is progressively resorbed and replaced by host bone during the osteo-remodeling process.

Indications for Use: NanoFUSE® DBM is indicated to be gently placed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure (i.e., the extremities, pelvis and posterolateral spine). These defects may be surgically created osseous defects or osseous

defects created from traumatic injury to the bone. NanoFUSE® DBM must be used with autograft as a bone graft extender in the posterolateral spine. The product provides a bone graft substitute that remodels into the recipient's skeletal system.

Technological Characteristics:

The applicant version of NanoFUSE® DBM is identical to the currently legally marketed medical device NanoFUSE® DBM, also manufactured by Nanotherapeutics, Inc. with respect to technological characteristics. NanoFUSE® DBM is comprised of human demineralized bone matrix (DBM) and synthetic calcium phosphor-silicate particulate material particles (45s5 bioactive glass), both coated with gelatin derived from porcine skin. It is provided dry and is reconstituted at the point of use into a paste-like, malleable form that can be molded or manipulated into bony defects.

NanoFUSE® DBM is reconstituted by the addition of fluid and waiting at least 30 seconds before expelling the contents from the syringe. At 30 seconds, the product extrudes as a very fluid paste and, with time, the gelatin carrier absorbs the fluid, becomes progressively thicker, and eventually sets in a rubbery mass.

Comparison Feature	**NanoFUSE® DBM - Predicate**	**NanoFUSE® DBM - Applicant**
Form	Syringe	Same
Materials of Construction	DBM, bioactive glass, gelatin	Same
Comparable Sizes	Yes	Yes
Osteoinductivity Assay	Cell bioassay	*in vivo* athymic rat implant or cell bioassay
Sterility	Yes – Radiation	Same
Anatomic Sites	Extremities, pelvis	Extremities, pelvis, posterolateral spine

Safety and Effectiveness:

NanoFUSE® DBM has a history of safe and effective clinical use. Additionally, biocompatibility testing and *in vitro* bench testing has previously been conducted to evaluate the biological safety and performance characteristics of NanoFUSE® DBM according to ISO 10993. The use of NanoFUSE® DBM in the posterolateral spine was evaluated *in vivo*.

Substantial Equivalence:

The use of NanoFUSE® DBM in the spine does not alter the fundamental scientific technology of the device. The use of NanoFUSE® DBM in the spine has been evaluated *in vivo*, and found to be substantially equivalent to cleared predicate devices.